

**REMARKS**

Claims 1, 4-17, 22-25, 31, 32 and 37-50 are currently pending in this application. Claims 7-16, 22-25, 31, 32, 37-42, 44 and 45 are withdrawn from consideration. Claims 1, 43 and 46-50 have been amended herein. This amendment is in accordance with the specification as originally filed, see page 17, lines 10-28, for disclosure of how to prepare monoclonal antibodies. Accordingly, no new matter is introduced by this amendment, and entry is respectfully requested.

**CLAIM OBJECTIONS**

Claims 47-49 stand objected to for purportedly being of improper dependent form for failing to further limit the subject matter of a previous claim. By limiting these claims to monoclonal antibodies that bind to an epitope within the identified range of amino acid residues, these claims further define the subject matter of Claim 46.

**CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 46-50 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Specifically, the Examiner asserts that the application does not reasonably convey to those of skill in the art that the antibodies claimed herein are antibodies that bind to an epitope in the ubiquitination regulating domain of the amino acid residues identified, thus, residues 1-250 of SEQ ID NO.: 1 (Claim 46), residues 50-140 (Claim 47), residues 1-140 (Claim 48) and residues 140-250 (Claim 49). The Examiner asserts that the specification as originally filed conveys to those of skill in the art recognition of antibodies that bind to an epitope in a ubiquitination-regulating domain that comprises the recited residues, rather than consists of those residues. Respectfully, Applicants note, initially, that the rejection is based on a hyper-technical reading of the statute. If Applicants disclose a ubiquitination range that comprises, the sequence of amino acids 1-250 of SEQ ID NO.: 1, that is the minimum sequence defined. Certainly, Applicants are entitled, on the basis of that disclosure, to claim no more than the minimum. The rejection is traversed on this ground.

Resolution of this issue is, in any event, unnecessary. The Examiner's attention is respectfully directed, e.g., to page 16 of the specification as originally filed. Therein, the application recites:

In another embodiment, antibodies to a polypeptide comprising residues 1-140 of a human TSG101 protein, e.g., amino acid residues 1-140 of SEQ ID NO.: 1, are produced. In yet another embodiment, antibodies to a polypeptide comprising amino acid residues 140-250 of a human TSG101 protein, e.g., amino acid residues 140-250 of SEQ ID NO.: 1 are produced. In still another

embodiment, antibodies to a polypeptide comprising residues 50-140 of a human TSG101 protein, e.g., amino acid residues 50-140 of SEQ ID NO.: 1 are produced. (Emphasis supplied.)

Thus, the specification, as originally filed, calls out this specific range that consists of the identified amino acid residues recited in each of the claims rejected. Withdrawal of the rejection is respectfully requested.

**REJECTIONS OF CLAIMS 1, 4, 6 AND 43 UNDER 35 U.S.C. § 102(B)**

Claims 1, 4-6, 43 and 46-50 stand rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by U.S. Patent No. 5,891,668 (**Li et al.**) as evidenced by **Pornillos et al.** (The EMBO Journal, Vol. 21, pp. 2397-2406 (2002)). Claims 1, 4-6, 43 and 46-50 stand rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by United States Patent No. 5,892,016 (**Brie et al.**). These rejections are respectfully traversed.

Applicants note initially that reliance on **Pornillos et al.**, as evidence for what is taught by **Li et al.**, or for any other purpose, is improper. **Pornillos et al.** in fact became available as a reference only months after Applicants' actual filing date of January 18, 2002. It is not evidence of the understanding of those of skill of the art as of the filing date Applicants are entitled to herein. As **Li et al.**, does not teach, as recognized by the Examiner, an antibody that binds to an epitope in the specific range, the rejections are respectfully traversed. In this respect, Applicants note that the Examiner's advanced rejection is not for obviousness, but for anticipation. As one

of ordinary skill in the art could easily prepare an antibody, according to the teaching of **Li et al.**, that binds to the coiled domain, the leucine zipper or the proline rich domains of TSG101, without preparing an antibody that binds specifically to an epitope in the ubiquitination-regulating domains of TSG101, the claims are simply not taught by the reference.

The Examiner's assertion that this "claimed limitation does not appear to result in a manipulative difference between the prior art and the claims" is not clearly understood. Simply because one of skill in the art, following the teaching of **Li et al.**, or **Brie et al.**, might prepare an antibody that accidentally binds to an epitope in a ubiquitination regulating domain of TSG101 by preparing an antibody directed to the proline rich region of TSG101 does not mean the same is taught. As the references, as the Examiner's acknowledges, is silent as to this feature of the claims, the references must necessarily inherently teach that feature, or the rejection cannot be maintained. It is quite clear from the references that they do not inherently teach this, that is, they specifically teach features for an antibody epitope that would not be in the ubiquitination-regulating domain of TSG101, within the specific amino acid sequence as recited.

Further, Applicants respectfully note that all antibodies recited in the claims presented are monoclonal antibodies. Accordingly, to the extent that prior to the amendment, the Examiner's characterization of the antibodies claimed "encompass monoclonal antibodies which are clearly taught by **Brie et al.** has applicability to the rejection", this concern is mooted by the amendment advanced.

Respectfully, the final substantive sentence of the outstanding Office Action indicates the basic failure of the two rejections for anticipation. If Applicants were merely claiming an unknown but inherent function of the prior art, that is, claiming antibodies that inherently bound an epitope within the ubiquitination region of TSG101 as defined by the sequence amino acid residues 1-250, 40-150, etc., then the Examiner's position would be entitled to due consideration. It is the burden of the Office, however, to demonstrate inherency, it is not Applicants' burden to show that undeposited, prophetic antibodies that clearly may not bind to an epitope within the indicated ubiquitination domains, lack Applicants' properties.

Should the Examiner elect to persist in the rejection, he is respectfully requested to indicate that specific antibody, by epitope, that he asserts is taught by **Li et al.** or **Brie et al.** to anticipate the claims (or if multiple such antibodies are taught, at least one) so that Applicants can make the requisite comparison. In the absence of such identification, the rejection may not be maintained.

**CONCLUSION**

All outstanding issues have been resolved by amendment or otherwise overcome by argument. As the claims are in condition for allowance an early and favorable action thereon is respectfully requested. If the Examiner believes a telephone conference could advance prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

/Steven B. Kelber/  
Steven B. Kelber  
Reg. No. 30,073  
Customer No. 22,506

**JAGTIANI + GUTTAG**  
Democracy Square Business Center  
10363-A Democracy Lane  
Fairfax, Virginia 22030  
(703) 563-2011 (direct)  
(703) 591-2664 (main)  
(703) 591-5907 (fax)  
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